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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,730	02/10/2000	Merry R. Sherman	MVIEW.0050A	4303

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[REDACTED] EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
1652	14

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/501,730	SHERMAN ET AL.	
	Examiner	Art Unit	
	Yong Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on March 8, 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 29-32 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10,17-28 and 33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed on March 8, 2002, has been entered.

Claims 1-33 are pending.

Election/Restrictions

Claims 11-16 and 29-32 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Applicant's arguments filed March 8, 2002 have been fully considered but they are not persuasive.

Claim Objections

Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Applicants argue that claim 10 does further limit the subject matter of claim 1 and claim 4 (Remarks, page 9, 2nd paragraph). The examiner disagrees.

Claim 1 is drawn to only full-length enzymes and not fragments. Also, claim 10 is not drawn to only truncated molecules because claim 10 is drawn to uricases comprising a truncated amino and/or carboxyl terminus.

Claim Rejections - 35 USC § 112

Claims 5, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 5 and 9, applicants argue that knowing the sequence of naturally occurring forms of uricase enables one skill in the art to identify sequences that fall within the claim limitation "substantially the sequence" of porcine, bovine, ovine or baboon liver uricase (Remarks, page 8, 2nd paragraph). The examiner disagrees. The metes and bounds of the claim are still unclear because various polypeptides can be "substantially" the sequence of a porcine, bovine, ovine, or baboon liver uricase and many polypeptides can contain a portion of porcine and baboon liver uricases.

Regarding claim 10, applicants argue that ".comprises an amino terminal and a carboxy terminus" is not redundant because the recitation of the termini affords proper antecedent basis for the latter half of the claim and that not all polypeptides have an amino and carboxyl terminus (Remarks, page 8, 3rd paragraph). The examiner

disagrees. While it is true that some polypeptides do not have an amino and carboxyl terminus, uricase does have an amino and carboxyl terminus. The claim is drawn to an uricase comprising an amino terminus and a carboxyl terminus in the first half of the claim. The latter part of the claim stipulates that one or both of the termini are truncated or removed, which does not satisfy the requirement that the uricase possess an amino terminus and a carboxyl terminus.

Claim Rejections - 35 USC § 102

Claims 1-8, 17-28 and 33 remain rejected under 35 U.S.C. 102(b) as being anticipated by R&D Focus Drug News.

Applicants argue that the R&D Focus Drug News reference does not satisfy the criteria for anticipation nor satisfy the criteria for an enabling disclosure (Remarks, page 3, 1st paragraph). Applicants also argue that the unfractionated PKS uricase received from Bio-Technology General Limited and the claimed invention is patentably distinct (Remarks, page 3, 2nd paragraph). The examiner disagrees.

The specification teaches that the unfractionated PKS of SEQ ID NO:3 of the instant invention was obtained from Bio-Technology General Limited (page 16, line 21) and the pegylated recombinant uricase of the reference belongs to Bio-Technology. Because the referenced uricase is used as a therapeutic composition in humans, one skilled in the art would recognize that said uricase is free of large aggregates. Applicants have not established that the uricase of the R&D Focus Drug News is patentably distinct from the PKS uricase of the instant invention.

Claims 1-8, 17-28 and 33 remain rejected under 35 U.S.C. 102(b) as being anticipated by Puricase™ Registration No. 2,246,623.

Applicants argue that the R&D Focus Drug News reference does not satisfy the criteria for anticipation nor satisfy the criteria for an enabling disclosure (Remarks, page 3, 1st paragraph). Applicants also argue that the unfractionated PKS uricase received from Bio-Technology General Limited and the claimed invention is patentably distinct (Remarks, page 3, 2nd paragraph). The examiner disagrees.

The owner of Puricase™ is Mountain View Pharmaceuticals, INC., the assignee of the instant invention and Puricase™ was first used in commerce from December 17, 1998 (U.S. Trademark, Registration No. 2,246,623). Because the referenced uricase is used as a therapeutic composition in humans, one skilled in the art would recognize that said uricase is free of large aggregates. Applicants have not established that the Puricase™ is patentably distinct from the PKS uricase of the instant invention.

Claim Rejections - 35 USC § 103

Claims 1, 4 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Puricase™ (Registration No. 2,246,623) in view of Wu et al.

Applicants argue that there is no motivation to combine the Puricase™ reference and the Wu et al. reference because uricase is not a copper binding enzyme (Remarks, page 6, 2nd paragraph). The examiner disagrees. It is well known in the art that uricases or urate oxidases are copper binding proteins (Wu et al. – page 9413, 2nd column). One would be motivated to replace a residue with a conserved residue

because conserved amino acids very often impart the characteristic property of an enzyme and because histidines play a role in binding copper and uricase is a copper binding enzyme.

Claims 1, 4 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over PuricaseTM (Registration No. 2,246,623) in view of Wu et al.

Applicants argue that neither the PuricaseTM nor the Wu et al. reference teaches a truncated uricase alone or in combination and does not suggest the claimed invention because SEQ ID NO:1(porcine) and SEQ ID NO:2 (baboon) of the instant invention are the same number of amino acids (Remarks, page 7, 3rd paragraph). The examiner does not see the relevance of the statement.

Wu et al. teach that porcine urate oxidase is six amino acid residues shorter than that of rat uricase (page 9414, 2nd column) but the two uricases are highly conserved throughout the coding region (page 9413, 4th paragraph). Claims 1, 4 and 10 are drawn to a wide genus of uricase from any source. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a functional uricase of a smaller size by deleting residues from both N -terminus. The motivation is to determine whether residues at the N-terminus are important for uricase activity and to use a smaller functional fragment of uricase in view of convenience.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-746-7240 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

May 17, 2002



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY DIVISION 1303